UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,289	03/19/2004	Joseph A. Hedrick	DX0757KB	7827

24265 7590 08/09/2005

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER	
ULM, JOHN D	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,289	HEDRICK ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/18/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 8 are pending in the instant application.

2) Claims 1 to 8 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a putative chemokine receptor protein identified therein as "BLRx" and the protein encoded thereby. The instant application does not disclose a credible biological role of this protein or its significance, beyond the fact that it is structurally related to proteins which are known in the art to be receptors for chemokines and its expression level in fibroblasts increases during would healing. The instant specification does not identify any ligand for a receptor of the instant invention nor does it identify a specific physiological process which one could reasonably associate with that receptor in light of the evidence of record. An invention must be useful in currently available form. Because the instant specification does not disclose the identity of at least one ligand for a receptor of the instant invention or provide a reasonable basis to support a conclusion that this protein is involved in a specific manner in at least one specific physiological process which one would wish to modulate for clinical effect, the claimed nucleic acid encoding that protein is not useful without further research and inventive contribution.

The text on pages 72 and 73 of the instant specification discloses that the "BLRx" protein described therein is constitutively expressed in dermal fibroblasts, and that the level of expression of this protein by fibroblasts is elevated during wound healing. It is noted that the evidence presented therein did not measure the expression levels of other proteins known to be expressed by fibroblasts before and after dermal wounding.

One of ordinary skill in the art of physiology knows that wound healing is inherently a proliferative process in which the cells involved therein, such as fibroblasts, function at a metabolically higher level than during periods when healing does not occur. Therefore, one would conclude that the level of expression of most, if not all of the proteins that are naturally expressed by a resting fibroblast would increase upon the activation of that fibroblast as occurs in the would healing process.

Further, one would reasonably conclude that all of the proteins expressed by a fibroblast are "involved" in would healing, since cells in nature do not generally produce "useless" gene products. However, the instant specification does not explain precisely how "BLRx" affects the healing process. Because different chemokines are known to elicit a variety of responses from the cells upon which they act, and the nature of the response depends upon the specific chemokine and the type of cell to which it is being administered, one can not predict the consequences of activating a particular chemokine receptor on a particular type of cell until a ligand for that receptor has been identified and it effects upon that cell type have been observed. Whereas one could readily employ a "BLRx" protein of the instant invention in an assay to identify an agonist thereto the information obtained thereby would be of little use until one discovers how the activation of "BLRx" affects the activity of a fibroblast. Because the instant specification has failed to disclose how the agonist activation of a putative receptor protein of the instant invention affects the activity of a fibroblast when administered thereto an artisan would have no way of predicting what effects the administration of that ligand to an organism would have. If one can not predict the

effects that the administration of an agonist of the putative receptor of the instant invention is going to have on an organism then it is unclear as to what practical benefit is derived by the public from the identification of that agonist.

It is clear from the instant specification that the receptor protein described therein as "BLRx" is what is termed an "orphan chemokine receptor" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to

engross what may prove to be a broad field", and "a patent is not a hunting license", " [i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to an isolated protein of as yet undetermined function or biological significance. There is no evidence of record that would support a conclusion the a protein of the instant invention is causally associated with abnormal proliferation, regeneration, degeneration or atrophy as asserted on page 47 of the instant specification. Until some actual and specific significance can be attributed to the protein identified in the specification as "BLRx", the instant invention is incomplete. The protein of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as G protein-coupled receptors. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit or induce its activity is clearly to use it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for "BLRx" then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3) Claims 1 to 8 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for

those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4) Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is vague and indefinite because the limitation ""is a 3-fold or less substituted form" is not defined in the specification and has no art-recognized meaning in the art of molecular biology.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1800